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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,867	02/14/2005	Amram Eizenfeld	415/14	2989
24101	7590	12/14/2007		
BRUCE E. LILLING LILLING & LILLING PLLC P.O. BOX 560 GOLDEN BRIDGE, NY 10526			EXAMINER NIA, ALIREZA	
			ART UNIT 3739	PAPER NUMBER
			NOTIFICATION DATE 12/14/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/524,867

Applicant(s)

EIZENFELD ET AL.

Examiner

Alireza Nia

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 09/26/05; 10/12/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations in claim 5 are unclear and vague. With respect to the recitations "Whereby the sleeve is removed from the proximal part of the endoscope" and "a further part of the sleeve extends away from the bunched portion in the proximal direction so as to cover the distal part of the endoscope", if the sleeve is already removed from the proximal portion of the endoscope in the proximal direction, it is unclear how the sleeve covers the distal end of the endoscope.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 18, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Tovey 6,416,462.**

5. With respect to claim 1, Tovey discloses an apparatus 10 for sheathing an endoscope 106,110, comprising a dispenser 14, having entry and exit ports (figs., 2,5) defining a transit passage through which the endoscope 106,110 may pass (fig. 2, col. 3, lines 58-65), and a

flexible sleeve 12, at least a portion of which is bunched (col. 3, lines 15-22) in a vicinity of the dispenser 14 (fig. 1), the sleeve 12 comprising a distal end 18, which is closed (col. 3, line 5), and a proximal end 16, which is open (col. 3, line 3) and fixed to the dispenser 14 so that as the endoscope 106,110 is advanced in a distal direction through the transit passage 19 (col. 3, line 1), the endoscope 106,110 enters into the sleeve 12 through the proximal end 16,A and engages the distal end 18 of the sleeve 12, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part 110 of the endoscope (fig. 5) that protrudes through the exit port (col. 4, lines 32-38).

6. With respect to claim 18, Tovey discloses an apparatus 10 for endoscopy (col. 2, lines 58-61) comprising an endoscope 106,110, which is adapted to be inserted into a body passage of a patient (fig. 6, col. 2, lines 58-61) and a sleeve assembly which comprises a dispenser 14, having entry and exit ports (figs. 2,5) defining a transit passage through which the endoscope 106,110 may pass (fig. 5), and a flexible sleeve 12, at least a portion of which is bunched (col. 3, lines 15-22) in a vicinity of the dispenser 14 (fig. 1), the sleeve 12 comprising a distal end 18, which is closed (col. 3, line 5), and a proximal end 16, which is open (col. 3, line 3) and fixed to the dispenser 14 so that as the endoscope 106,110 is advanced in a distal direction through the transit passage 19 (col. 3, line 1), the endoscope 106,110 enters into the sleeve 12 through the proximal end 16,A and engages the distal end 18 of the sleeve 12, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part 110 of the endoscope (fig. 5) that protrudes through the exit port (col. 4, lines 32-38).

7. With respect to claim 36, Tovey discloses a method for protecting an endoscope 106,110 from contamination comprising providing a flexible sleeve 12 comprising a distal end 18, which is closed (col. 3, line 4), and a proximal end 16, which is open (col. 3, line 3), wherein at least a

portion of the sleeve 12 is bunched in a compaction region (col. 3, lines 15-23), inserting a distal part 110 of the endoscope 106,110 into the proximal end and through the bunched portion of the sleeve 12 so as to engage the distal end (fig. 5), and advancing the endoscope 106,110 through a body opening of a patient (fig. 6) into a body passage while extending the bunched portion of the sleeve so as to cover the distal part 110 of the endoscope 106,110 that extends through the body opening into the body passage (col. 4, lines 48-57, fig. 6).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1-4, 18-22 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore 2001/0007060 in view of Szabo 5,325,846.**

10. With respect to claim 1, Fiore discloses an apparatus for sheathing an endoscope 14 comprising a dispenser 10 having entry and exit ports (fig. 1) defining a transit passage through which the endoscope 14 may pass. Fiore also discloses a flexible sleeve comprising a distal and proximal end [0036-0037].

11. However, Fiore does not disclose at least a portion of the flexible sleeve to be bunched in a vicinity of the dispenser, the sleeve comprising a distal end, which is closed, and a proximal end, which is open and fixed to the dispenser so that as the endoscope is advanced in a distal direction through the transit passage, the endoscope enters into the sleeve through the proximal

end and engages the distal end of the sleeve, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part of the endoscope that protrudes through the exit port.

12. Szabo teaches a flexible sleeve 22, at least a portion of which is bunched (col. 3, lines 49-51) in a vicinity of a dispenser, the sleeve 22 comprising a distal end 34 (fig. 1), which is closed , and a proximal end 14,36, which is open and fixed to the dispenser (fig. 1) so that as an endoscope is advanced in a distal direction through the transit passage, the endoscope enters into the sleeve 22 through the proximal end 14 and engages the distal end 34 of the sleeve 22, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part of the endoscope that protrudes through the exit port (col. 2, lines 65-68).

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Fiore in view of the limitations taught by Szabo in order to provide an improved device that eases the draping process of endoscopic equipment allowing operating personnel to easily and expeditiously drape an endoscope, as taught by Szabo (col. 2, lines 24-26 et seq. lines 34-35).

14. With respect to claim 18, Fiore discloses an apparatus for endoscopy comprising an endoscope 14, which is adapted to be inserted into a body passage of a patient, and sleeve assembly which comprises a dispenser 10, having entry and exit ports (fig. 1) defining a transit passage through the endoscope 14 may pass.

15. However, Fiore does not disclose at least a portion of the flexible sleeve to be bunched in a vicinity of the dispenser, the sleeve comprising a distal end, which is closed , and a proximal end, which is open and fixed to the dispenser so that as the endoscope is advanced in a distal direction through the transit passage, the endoscope enters into the sleeve through the proximal

end and engages the distal end of the sleeve, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part of the endoscope that protrudes through the exit port.

16. Szabo teaches a flexible sleeve 22, at least a portion of which is bunched (col. 3, lines 49-51) in a vicinity of a dispenser, the sleeve 22 comprising a distal end 34 (fig. 1), which is closed, and a proximal end 14,36, which is open and fixed to the dispenser (fig. 1) so that as an endoscope is advanced in a distal direction through the transit passage, the endoscope enters into the sleeve 22 through the proximal end 14 and engages the distal end 34 of the sleeve 22, thus causing the bunched portion of the sleeve to be extended so as to cover a distal part of the endoscope that protrudes through the exit port (col. 2, lines 65-68).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Fiore in view of the limitations taught by Szabo in order to provide an improved device that eases the draping process of endoscopic equipment allowing operating personnel to easily and expeditiously drape an endoscope, as taught by Szabo (col. 2, lines 24-26 et seq. lines 34-35).

18. With respect to claim 36, Fiore discloses a flexible sleeve comprising a distal end and a proximal end, the insertion of a distal part of an endoscope 14 into the sleeve, and advancing the endoscope 14 through a body opening of a patient into a body passage 12 (fig. 1).

19. However, Fiore does not disclose the flexible sleeve to comprise distal end which is closed and a proximal end which is open, wherein at least a portion of the sleeve is bunched in a compaction region, inserting the distal end of the endoscope into the proximal end and through the bunched portion of the sleeve so as to engage the distal end and while advancing the endoscope extending the bunched portion of the sleeve so as to cover the distal part of the endoscope.

20. Szabo teaches a flexible sleeve 22 which comprises a distal end 34 which is closed (fig. 1) and a proximal end 14 which is open (fig. 1), wherein at least a portion of the sleeve 22 is bunched in a compaction region 17 (figs. 1,2, col. 3, lines 49-55), inserting the distal end of an endoscope into the proximal end 34 and through the bunched portion of the sleeve so as to engage the distal end and while advancing the endoscope extending the bunched portion of the sleeve so as to cover the distal part of the endoscope (col. 2, lines 65-68).

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Fiore in view of the limitations taught by Szabo in order to provide an eased process for draping of endoscopic equipment allowing operating personnel to easily and expeditiously drape an endoscope, as taught by Szabo (col. 2, lines 24-26 et seq. lines 34-35).

22. With respect to claim 2, 19, and 37, Fiore in view of Szabo disclose the invention as discussed above. Fiore further teaches the dispenser is adapted to be placed so that the exit port is adjacent to a body opening 15 of a patient 12, whereby the distal part of the endoscope that is covered by the sleeve extends through the body opening into a body passage 15 of the patient 12 (fig. 1).

23. With respect to claims 3, 5, 20, 22, and 38, Fiore in view of Szabo disclose the invention as discussed above. Szabo further teaches the sleeve 22 to be a unitary piece; therefore, the distal end of the sleeve would have inherently been adjacent to the bunched up portion of the sleeve, since they are both of one piece. With respect to the recitation "the sleeve is adapted to extend away from the bunched portion in a proximal direction" and "a further part of the sleeve extends away from the bunched portion in the proximal direction", it would have been obvious to one of ordinary skill in the art at the time of the invention that in order to dispense the sleeve,



one skilled in the art would have needed to unfold the sleeve from its bunched state; thus, requiring from one skilled in the art to have extended the sleeve away from the bunched portion in a proximal direction in order to cover the distal part of an endoscope.

24. With respect to claims 4 and 21, Fiore in view of Szabo disclose the invention as discussed above. Fiore in view of Szabo do not disclose the dispenser being adapted to capture the sleeve as the endoscope is retracted through the transit passage.

25. Szabo further teaches grooves 26 which can capture and secure the sleeve 22 (col. 3, lines 34-36).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Fiore in view of Szabo, further in view of the limitations taught by Szabo in order to provide an improved device that eases the draping process of endoscopic equipment allowing operating personnel to easily and expeditiously drape an endoscope, as taught by Szabo (col. 2, lines 24-26 et seq. lines 34-35).

27. With respect to the recited steps in claims 36 and 38, since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Fiore in view of Szabo in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

28.

**29. Claims 6, 7, 23, 24 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey 6,416,462 in view of Perkins 5,496,259.**

30. Tovey discloses the invention as discussed above. However, with regards to claims 6, 23, and 39, Tovey does not disclose the dispenser to be adapted to capture the sleeve as the endoscope is retracted through the transit passage in a proximal direction, so that the sleeve is removed from a proximal part of the endoscope that has been retracted through the entry port, and the removed sleeve is gathered in the dispenser. Also with regards to claims 7, 24, and 40, Tovey does not disclose the dispenser to be adapted to gather substantially all of the sleeve, so that after the distal part of the endoscope has been retracted through the entry port, substantially all of the sleeve is contained within the dispenser.

31. Perkins teaches a dispenser that is adapted to capture a sleeve as an endoscope is retracted through a transit passage in a proximal direction, so that the sleeve is removed from a proximal part of the endoscope that has been retracted through the entry port, and the removed sleeve is gathered in the dispenser (fig. 4, col. 3, lines 63-67 and col. 4, lines 1-10).

32. It would have been obvious to one ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of the limitations taught by Perkins to provide a sterile sheath which minimizes risk of contact with surfaces contaminated by a patient's body fluids during surgery, as taught by Perkins (col. 2, lines 6-8).

33. With respect to the recitation, "The dispenser is adapted to gather substantially all of the sleeve, so that after the distal part of the endoscope has been retracted through the entry port, substantially all of the sleeve is contained within the dispenser" in claims 7, 24, and 40, it would have been obvious to one of ordinary skill in the art at the time of the invention to have increased the length or diameter of the dispenser in order to allow the dispenser to contain substantially all

of the sleeve, since it has been held that, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

34. With respect to the recited steps in claims 39 and 40, since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Tovey in view of Perkins in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

**35. Claims 8-13, 25-31 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey 6,416,462 in view of Takahashi 5,050,585.**

36. With regards to claims 8, 25, and 41, Tovey discloses the invention as discussed above. However, Tovey does not disclose an external sleeve, fixed to the dispenser, which is adapted to be extended from the dispenser when the endoscope is retracted through the transit passage, so that the external sleeve covers the flexible sleeve that was extended to cover the distal part of the endoscope.

37. Takahashi discloses an external sleeve 10a (col. 3, lines 40-64) fixed to a dispenser adapted to be extended from the dispenser over an endoscope.

38. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of the limitations taught by Takahashi in order to

provide a practical sheathed endoscope having an insert tube which is capable of stably retaining therein a channel tube and which can readily be produced, as taught by Takahashi (col. 1, lines 65-68).

39. With regards to claims 9 and 26, Tovey in view of Takahashi disclose the invention as discussed above. With respect to the locations of fixing the flexible sleeve and the external sleeve to the dispenser, it would have been obvious to one of ordinary skill in the art at the time of the invention to have adapted the dispenser accordingly and have rearranged the sleeves on the dispenser as necessary in order to achieve the desired outcome with respect to the endoscope, since it has been held that, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

40. With respect to claims 10 and 42, Tovey discloses the invention as discussed above. Takahashi further teaches the sleeve 10a is adapted to be inflated while an endoscope is advanced through a transit passage (col. 4, lines 14-19).

41. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of the limitations taught by Takahashi in order to provide a practical sheathed endoscope having an insert tube which is capable of stably retaining therein a channel tube and which can readily be produced, as taught by Takahashi (col. 1, lines 65-68).

42. With respect to claims 11 and 43, Tovey in view of Takahashi disclose the invention as discussed above. With respect to the recitation “the sleeve is adapted to be deflated”, since Takahashi teaches the sleeve 10a to be inflatable, then it would have been obvious to one ordinary skill in the art at the time of the invention that if a sleeve was adapted to be inflated,

then it was also adapted to deflated. With respect to the recitation “while the endoscope is retracted proximally through the transit passage”, it would have been obvious to one ordinary skill in the art at the time of the invention to have deflated the sleeve upon retracting the endoscope through the transit passage since, it has been held that rearranging parts of an invention involves only routine skill in the art, *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

43. With respect to the recited steps in claims 41-43 since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Tovey in view of Takahashi in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

44. With respect to claims 12, 27, 28, and 30, Tovey in view of Takahashi disclose the invention as discussed above. Takahashi further teaches a dispenser comprising a channel 11b contained within an endoscope communicating with a sleeve via 21, for inflating the sleeve while the endoscope is advanced and for applying suction to the sleeve while the endoscope is retracted via 21 (col. 3, lines 60-61).

45. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of Takahashi, further in view of the limitations taught by Takahashi in order to provide a practical sheathed endoscope having an insert tube

which is capable of stably retaining therein a channel tube and which can readily be produced, as taught by Takahashi (col. 1, lines 65-68).

46. With respect to claims 13 and 29, Tovey in view of Takahashi disclose the invention as discussed above. With respect to the recitation “the entry port is adapted to fit snugly around the endoscope”, it would have been obvious to one of ordinary skill in the art at the time of the invention to have sized the entry port such that it would have a compatible and sealed so as to prevent leakage, since it has been held that, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

47. With respect to claim 31, Tovey in view of Takahashi disclose the invention as discussed above. With respect to the recitation “the channel is contained within the dispenser, alongside of the endoscope”, it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

**48. Claims 14, 32, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey 6,416,462 in view of Butler 2003/0069472.**

49. Tovey discloses the invention as discussed above. However, Tovey does not disclose a working channel extending through the sleeve alongside the endoscope, the working channel comprising distal and proximal extremities, wherein the distal extremity is fixed to the distal end of the sleeve, and the proximal extremity protrudes from the dispenser.

50. Butler teaches a working channel 83 extending through a sleeve alongside an endoscope, the working channel comprising distal and proximal extremities (fig. 14), wherein the distal

extremity is fixed to a distal end of a sleeve and the proximal extremity protruding from a dispenser (fig. 14).

51. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of the limitations taught by Butler in order to provide an insertion device to aid introduction of a probe and/or an overtube into a passageway to facilitate performance of colonoscopy more easily and more efficiently, especially without the need for expensive, cumbersome imaging equipment, as taught by [0015].

52. With respect to the recited steps in claim 44, since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Tovey in view of Butler in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

**53. Claims 15, 33, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey 6,416,462 in view of Butler 2003/0069472 further in view of Carrillo 6,663,598.**

54. Tovey in view of Butler disclose the invention as discussed above. However, Tovey in view of Butler do not disclose a sealing element, which is adapted to seal the proximal extremity of the working channel while the endoscope is removed from the dispenser.

55. Carrillo teaches a sealing element 10 which is adapted to seal the proximal extremity of a working channel (col. 3, lines 51-54).

56. It would have been obvious to one ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of Butler, further in view of the limitations taught by Carrillo in order to provide an improved endoscope seal that effectively inhibits the egress of fluid from the working channel of an endoscope, as taught by Carrillo (col. 2, lines 14-17).

57. With respect to the recited steps in claim 45, since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Tovey in view of Butler in view of Carrillo in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

**58. Claims 16-17, 34-35, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey 6,416,462 in view of Wilk 5,746,694.**

59. Tovey discloses the invention as discussed above. However, with respect to claims 16, 34, and 46, Tovey does not disclose the endoscope to include a working channel having distal and proximal outlets, and wherein the apparatus comprises an internal sleeve, which is adapted to be inserted through the working channel, the internal sleeve comprising distal and proximal extremities, wherein the distal extremity is fixed to the distal end of the sleeve, and the proximal extremity protrudes from the proximal outlet of the working channel. With respect to claims 17, 35, and 47, Tovey also does not disclose a sealing element which is adapted to seal the proximal extremity of the internal sleeve while the endoscope is removed from the dispenser.



60. Wilk teaches an endoscope to include a working channel having distal 20 and proximal outlets 18 (figs. 2A,B), and wherein the apparatus comprises an internal sleeve 10 (fig. 1), which is adapted to be inserted through the working channel via 22 (figs. 1, 2A,B, col. 5, lines 27-35), the internal sleeve 10 comprising distal and proximal extremities (fig. 2A, col. 5, lines 44-47), wherein the distal extremity is fixed to the distal end 26 of the sleeve 10 (fig. 2B), and the proximal extremity protrudes from the proximal outlet of the working channel via 18. With respect to claim 17, 35, and 47, Wilk also teaches a sealing element 32 (col. 5, lines 45-47) which is adapted to seal the proximal extremity of the internal sleeve 10 via 30 while an endoscope is removed from the dispenser.

61. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Tovey in view of the limitations taught by Wilk in order to provide a device for promoting cleanliness in endoscopic surgery while reducing the time spent on procedures to clean endoscopes, as taught by Wilk (col. 1, lines 59-61 et seq. 63-64).

62. With respect to the recited steps in claims 46-47, since the apparatus performs the recited methods, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided and used the apparatus of Tovey in view of Wilk in order to carry out the intended processes in order to achieve the intended results, since it has been held that where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

***Conclusion***

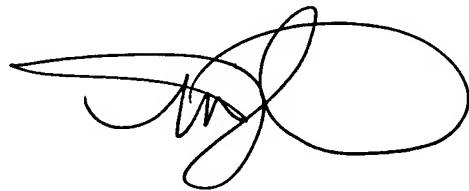
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alireza Nia whose telephone number is 571-270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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